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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/542,049	07/13/2005	Sylvain Diguet	4662-49	6355

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EXAMINER	
PALENIK, JEFFREY T	
ART UNIT	PAPER NUMBER
1615	
MAIL DATE	DELIVERY MODE
12/10/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/542,049	DIGUET ET AL.	
	Examiner	Art Unit	
	Jeffrey T. Palenik	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 July 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of Applicants' Amendments and Remarks filed 18 July 2008. The Examiner acknowledges the following:

New claim 24 has been added.

Claims 12-20 which were previously only withdrawn from consideration, are acknowledged as having been cancelled by Applicants.

Amendments have been made to pending claims 21 and 22. Support for the amendments was expressly provided and thus the Examiner acknowledges that no new matter has been added to the claims.

Thus, claims 21-24 now represent all claims currently under consideration.

PRIORITY

Applicants' continuity of priority has been verified via the documents previously submitted. The Examiner thanks Applicants for pointing out the incorrectly applied time requirement. As such, Applicants' effective U.S. filing date is thus extended to 27 March 2003.

INFORMATION DISCLOSURE STATEMENT

No new Information Disclosure Statement (IDS) have been submitted for consideration.

WITHDRAWN OBJECTIONS/REJECTIONS

Objection to the Specification

Applicants' amendments to both the Abstract and Title of the Invention render moot their objection. Thus said objections have been **withdrawn**.

Rejection under 35 USC 112

Applicants' amendments and remarks, render moot the rejections to claims 21 and 22, under 35 USC 112, second paragraph. Thus, said rejections have been **withdrawn**.

MAINTAINED REJECTIONS

The following rejections are maintained from the previous Office Action dated 1 February 2008:

CLAIM REJECTIONS - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 21 is rejected under 35 U.S.C. 102(b) as being anticipated by Scialpi (U.S. Patent 4,670,247).

The independent claim 21 is directed to a cross-linked beadlet whose core contains one or more of a fat-soluble vitamin, a carotenoid and a polyunsaturated fat wherein the surface region of the core contains less than 10% or less than 5% of the total active agent.

Such compositions are taught to be made by Scialpi. Claims 1-4 teach that the cross-linked beadlet core (e.g. particulate) is formed as a fat-soluble vitamin active particulate composition containing 20-30% of a vitamin. The core particulate composition formed, as stated earlier, inherently has a surface region to it. The teachings of Scialpi are silent to the presence of any percentage of any type of active agent on said inherent surface region. The individual droplets are collected in a mass of starchy powder in such a manner as to maintain separation of the vitamin-active particles (col. 1, lines 51-54). Since the starch-based collecting powder is not taught to contain any of the active ingredient(s), Scialpi teaches that the surface region contains less than either 10% or 5% of the total active ingredient present on the surface region of the beadlet.

Therefore each and every one of the limitations is met by the reference.

Claims 21 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Borenstein et al. (U.S. Patent 5,043,170).

The independent claim 21 is directed to a cross-linked beadlet whose core contains one or more of a fat-soluble vitamin, a carotenoid and a polyunsaturated fat wherein the surface region of the core contains less than 10% or less than 5% of the total active agent. The independent claim 22 is directed to the same composition, but is further limited by its

definition of ranges for concentrations of Vitamins A, D, E, a carotenoid, and a polyunsaturated fat.

Such compositions are taught to be made by Borenstein et al. Claim 1 teaches poultry feed particles comprising Vitamin D_3. Claims 3 and 4 further specify that the particles are in the form of beadlets. Said beadlets are also taught to be cross-linked (col. 4, lines 57-58). As with Scialpi, the beadlet composition formed by the invention of Borenstein et al., inherently has a surface region to it. Also like the teachings of Scialpi, the teachings of Borenstein are silent to the presence of any percentage of any type of active agent on said inherent surface region. Part B of Example 2 teaches blending an encapsulating agent and a plasticizer with water to make a 50% aqueous solution (col. 7, lines 63-64). The lipid phase containing the active vitamin D_3 is then encapsulated by the 50% aqueous solution. Since the lipid phase and not the aqueous phase is in possession of the active vitamin D_3, Borenstein teaches that the surface region contains less than either 10% or 5% of the total active ingredient present on the surface region of the beadlet. The independent claim 22 recites a limitation to the composition such that vitamin D is present in a total concentration ranging from 100,000 IU to 500,000 IU per gram of beadlet. Example 2 cites a composition for beadlets whose label cites 100,000 IU Vitamin D_3/gram (col.7, lines 59-60).

Therefore each and every one of the limitations is met by the reference.

CLAIM REJECTIONS - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scialpi (U.S. Patent 4,670,247) in view of Remington (19th ed.) and Hamer et al. (U.S. Patent 6,413,548).

The instant independent claims 21 and 22 are both directed to cross-linked beadlet compositions, as described above. The dependent claim 23 recites the following range limitations to the ingredients of the composition of claim 22:

30-45% vitamin A
0-2% vitamin D_3
5-15% 6-ethoxy-1,2-dihydro-2,2,4-trimethylquinolone (ethoxyquin)
25-35% gelatin
5-10% fructose
2-10% glycerine
0-1% edible fat
0-25% corn starch
5-10% calcium silicate
Water

Scialpi teaches such compositions in claims 1-4. However, claim 4 teaches the following specific compositional ranges:

20-30% of a vitamin
5-13% of an antioxidant
35-45% gelatin
2-20% of a reducing sugar
0-15% of a humectant
5-20% of a hydrophobic starch
Water to volume

As shown above, the limitation of 20-30% of a vitamin is taught in claim 4, which reads on the vitamin composition of the instant claim 23 since Vitamin D_3 may be absent from the composition. Ethoxyquin is taught as an antioxidant (col. 2, lines 35-39). Fructose is taught as a reducing sugar (col. 2, lines 25-26). Glycerin is taught as a humectant (col. 2, lines 38-39). Scialpi teaches that a preferred collecting powder for the composition consists substantially of a starch modified to include hydrophobic groups (col. 3, lines 7-11). Remington further teaches that starches, such as corn starch, are insoluble in cold water and that even when it is boiled with about 20 times its weight of hot water it does not become a solution (page 1414), thereby exhibiting hydrophobic properties. Scialpi teaches a composition is silent to fat, which reads on the instant composition since having 0% fat is possible. Scialpi, as discussed earlier, does not expressly teach calcium silicate as part of the composition. However, silicic acid, which is a functional equivalent to calcium silicate, is taught as being added to the starch-based collecting powder (col. 2, lines 60-64) used to

collect the composition into its beadlet form. Lastly, each of the Examples teaches the inclusion of distilled water in the beadlet formulations.

Hamer et al. teaches a stable encapsulant system comprising hydrophobic droplet particles further comprising vitamins, pigments and powders (claims 12, 13, and 15). The powders, which are taught between 5-50% and most preferably between 10-40%, can include corn starch or calcium silicate or both (col. 17, lines 18-35).

In view of the combined teachings of the prior art, one of ordinary skill in the pharmaceutical art would have been motivated to prepare a cross-linked beadlet product using a fat-soluble vitamin active agent such as Vitamin A or Vitamin D (e.g. Vitamin D_3) in combination with a mixture comprised of pharmaceutically acceptable humectants, antioxidants, sugars and powders with a reasonable expectation of stably forming the bioactive agent into a "cored" particulate formulation. Such would have been obvious in the absence of evidence to the contrary because Scialpi teaches the components of the instant composition in claim 4 and specific components throughout the disclosure, as referenced above.

However, neither of the references teaches adding the active ingredients in the amounts claimed by Applicant. The amounts of specific ingredients in a composition are clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ and reasonably would expect success. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve any of the desired results cited in the instant claims

22 and 23. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amounts would have been obvious at the time of Applicants' invention.

RESPONSE TO ARGUMENTS

Applicants' arguments with regard to the rejections of claim 21 under 35 USC 102(b) as being anticipated by Scialpi, claims 21 and 22 under 35 USC 102(b) as being anticipated by Borenstein et al., and claims 21-23 as being unpatentable over Scialpi in view of Remington and Hamer et al, have all been fully considered, but none are persuasive.

Applicants' traversal of all of the aforementioned rejections hinges on the allegation that the process steps which have been amended into independent claim 21 "are very important for the final distribution of the active ingredients in the beadlet" and that these attributes are neither taught nor suggested by Scialpi or Borenstein.

In response, the Examiner respectfully submits that that while the limitations amended into the claim and upon which Applicants' arguments are based do not render the claim necessarily improper, said limitations are directed to methods for preparing the instantly claimed composition. Stated another way, Applicants' arguments are directed towards the amended product-by-process limitations of the instant composition claims. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself" (see MPEP §2113).

Thus, for these reasons, Applicants' arguments are found unpersuasive. The above rejections is hereby maintained.

NEW REJECTIONS

The limitation recited by newly added claim 24 further limits the recited surface region concentration of the beadlet of claim 21 to less than 5% of the total active ingredient. Said limitation is still read upon by the art and rejections already made of record, as discussed herein above. Since the newly added limitation already stands rejected, **no new rejections are required.**

All claims have been rejected; no claims are allowed.

CONCLUSION

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

CORRESPONDENCE

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey T. Palenik whose telephone number is (571) 270-1966. The examiner can normally be reached on 7:30 am - 5:00 pm; M-F (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jeffrey T. Palenik/
Examiner, Art Unit 1615

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615